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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,117

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Daisuke Awakura

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

09/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,117	Applicant(s) AWAKURA ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-35 is/are pending in the application.
- 4a) Of the above claim(s) 14, 19 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 15-18, 20-25 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages / 06/08/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on July 15, 2009.

Status of Claims

Amendment of claims 11-34 and addition of claim 35 is acknowledged.

Claims 11-35 are currently pending and are the subject of this office action.

Claims 14, 19 and 26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

Claims 11-13, 15-18, 20-25 and 27-35 are presently under examination.

The following species, elected by Applicant in the reply filed on January 16, 2009, are under examination: potassium phosphite as the elected species for Compound A

Priority

The present application is a 371 of PCT/JP03/15543 filed on 12/04/2003, and claims priority to foreign application: JAPAN 2002-352697 filed on 12/04/2002.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated

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(Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (Maintained rejection)

Claims 11-13, 15-18, 20-25, 27-29, 31-34, new claim 35 and previously objected claim 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Staub et. al. (US 4,849,219, cited in prior office action) in view of Pirgozliev et. al. (European Journal of Plan Pathology (2002) 108:469-478, cited in prior office action).

The reasons for this rejection have been provided in the previous office action dated April 17, 2009, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that: Staub et al. concern microbicides. In the paragraph bridging columns 3 and 4, Staub et al. describe over twenty-five different fungicides. There is no teaching or suggestion in Staub et al. to pick two of the fungicides referred to in the Office Action out of such twenty-five different fungicides disclosed by Staub et al. Staub et al. list almost seventy different species of plants in column 5. There is no teaching or suggestion in Staub et al. to select wheat out of such seventy different plant

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species. Staub et al. list fifteen different fungi at the top of column 5, without any direction to choose fusarium from this list. Moreover, only selected species of fusarium produce DON. Due to the aforementioned deficiencies in Staub et al., the Pirgozliev et al. reference was applied. Pirgozliev et al. concern only a study wherein metconazole and azoystrobin, fungicides used for the control of Fusarium head blight, resulted in elevated concentration of deoxynivalenol (DON). Pirgozliev et al. do not teach or suggest any of the compounds effective for inhibiting production of mycotoxin by plant pathogenic fungi of cereals which are recited in applicants' claims.

Examiner's response: First: as mentioned in the previous office action: it would have obvious to have selected various combinations of various disclosed ingredients (potassium phosphate as the antifungal, Fusarium as the fungi and wheat as the cereal) from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

Second: if Pirgozliev would have taught a compound like potassium phosphate for inhibiting production of mycotoxin by plant pathogenic fungi of cereals, it would probably have been a 102 rejection instead of a 103. Pirgozliev clearly teaches that the source of DON is the presence of certain strains of Fusarium which are present in wheat (see title and abstract).

Applicant further argues: Pirgozliev et al. do not teach or suggest reducing DON to a safe level, such as 1.1 ppm or less (see applicants' claim 35).

Examiner's response: Pirgozliev teaches that the FDA recommends that DON concentrations should not exceed 1000 micrograms/kg (i.e. 1 ppm) in finished wheat products and should. Based on this, and since it is within the capability of the ordinary skilled in the art to modify amounts for a specific treatment and adjust those particular amounts to observed effectiveness, the skilled artisan would have been further motivated to determine the amount of potassium phosphite required in order to reduce the amount of DON below the level required by the FDA.

Applicant argues: As disclosed at the middle of page 4 of applicants' specification, it has been demonstrated that not all of the pathogenic fungi which cause Fusarium head blight produce 'DON contaminations. Accordingly, based on the knowledge involving Fusarium head blight, it is respectfully submitted that one of ordinary skill in the art would not know precisely what fungicide to apply to reduce DON to an acceptable safe level. The presently claimed invention selectively reduces DON to a level approved by the FDA, regardless of the presence or absence or the degree of Fusarium head blight of cereals. As discussed in the paragraph bridging pages 4 and 5 of the present specification, even when the Fusarium head blight of the cereals is controlled by combined application of various fungicidal agents, DON is frequently detected at more than 1.1 ppm.

In view of the above, it is respectfully submitted that one of ordinary skill in the art would not consider combining the references in an attempt to arrive at applicants' presently claimed invention. Even assuming *arguendo* that the references were

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combinable, it is respectfully submitted that such combination would lead one of ordinary skill in the art to the presently claimed invention.

Clearly, the presently claimed invention is not based on the fungicidal effects of various fungicides or the control or lack thereof of Fusarium head blight. This is clear from the data set forth in the specification, which is discussed herein below.

Then Applicant presents a series of data from the specification trying to back up the above statements.

Examiner's response: First, Pirgozliev clearly teaches that Fusarium is a destructive fungal disease of wheat and other small grain cereals. Then Pirgozliev teaches the strains that are most associated with the disease (see Introduction, left column). Then Pirgozliev further teaches that DON is one of the mycotoxins produced by Fusarium species (see page 469, right column, second paragraph). So it is clear that the source of DON are certain (although not all) strains of Fusarium.

Second: Applicant tries to make a point by differentiating the amount of fungi (i.e. Fusarium) present in wheat and the amount of DON. For example on pages 25 and 26 (see Applicant's response) Applicant concludes from the data of Table 5 that : "it is clear that application of potassium phosphite has a high inhibitory effect on the DON production, regardless of the presence or absence of the proliferation degree of the fungi for Fusarium head blight of cereals". However, in the non-treated group, there is a clear correlation between the amount of DON and amount of fungi, which corroborates the above statement, that the source of DON is Fusarium fungi. In the group that was treated with 5.6% potassium phosphite the amount of fungi increases up until day 21,

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and then reaches a plateau and the amount of DON was not detected at any point. This can be interpreted as follows: definitively, as stated above, Fusarium fungi is the source of DON. Potassium Phosphite controls some biological process in the Fungi that prevents further production of DON, while the Fungi still survives to a certain extent. In other words, the survival of Fungi and the production of DON by the Fungi are two relatively independent processes: the fungi can still grow and not produce more DON due to the inhibition of the mechanism of DON production by potassium phosphite. On the other hand, if potassium phosphite completely reduces the amount of Fusarium, there will not be any DON production. See for example Table 6 on page 28 of Applicant's response. On Table 6 it is clearly shown that the higher the concentration of potassium phosphite the lower the concentration of DON and the lower the amount of Fungi, except for the lower concentrations where the fungi seems to be constant. That simply indicates that within certain ranges of concentrations of potassium phosphite, like between 0.056% and 0.560%, the amount of DON decreases dramatically from 1.60 ppm to ND (Not Detected), while the amount of fungi remains more or less constant, however at the highest concentration of 2.8% potassium phosphite, the amount of Fungi also starts decreasing. This, again, confirms that there is a dose range wherein the production of DON by Fusarium is inhibited, while the growth of the Fusarium is not, and then by further increasing the amount of potassium phosphite, the amount of Fungi also starts decreasing.

In summary: by increasing the amount of potassium phosphite the amounts of both DON and Fusarium will decrease, although at a different pace.

Withdrawn Rejections and/or Objections

Claims objected.

Due to applicant's amendment of claim 30, the objection is now moot.

Objection of claim 30 is withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
August 30, 2009

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612